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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/616,448	07/08/2003	Jeffry G. Weers	0103.11	1036
21968	7590	10/25/2004	EXAMINER	
NEKTAR THERAPEUTICS 150 INDUSTRIAL ROAD SAN CARLOS, CA 94070			WEBMAN, EDWARD J	
			ART UNIT	PAPER NUMBER
			1617	

DATE MAILED: 10/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/616448

Applicant(s)

W/GER

Examiner

CJGBMAN

Group Art Unit

1617

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 7/8/03
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-20 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-20 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

Office Action Summary

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards et al WO 98/31346 in view of Vaghefi, Unger, and Burns et al.

Edwards et al. Discloses delivery of phospholipid matrix containing particles with a mass mean diameter between 5 and 30 microns and a tap (bulk) density of 0.4g/cm³ which together yield an aerodynamic diameter of the particles of between 1 and 5 microns for use in a method of administration employing a passive dry powder inhaler (see abstract, lines 3-9, p.6, lines 2-13, p.8 lines 11-21, p. 9, lines 12-13, p.11 lines 23-27, p.33, lines 23-29). Any agent can be incorporated (page 20 line 1-page 21 line 14). Over 35% of particles are considered respirable (page 34 lines 12-14). DPPC is specified (page 6 line 1). Enhanced delivery is disclosed (page 6 lines 24-25).

It would have been obvious to one of ordinary skill to deliver antibiotics using the method of Edwards to achieve the beneficial effect of enhanced delivery. As to the claimed distearyl phosphatidyl choline, Unger teaches its equivalence to DPPC as a Lipid stabilizer for active agents in methods of delivery including insufflation (column 38 lines 54-58, 63-64 and column 13 lines 11-18).

As to the claimed budesonide, Vaghefi teaches that it is deliverable by dry powder inhaler (title, column 13, line 10). Thus, one of ordinary skill would deliver budesonide with the inhalation method of Edwards in view of its deliverability by such a

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method as taught by Vaghefi, ^Aas to applicant's ^aclaimed properties, the disclosed inhaler of commerce in combination with the disclosed particles in Edwards provides the same delivery characteristics as claimed with like commercially available devices disclosed by applicants. Applicants have shown no criticality for the claimed property for tobramycin as opposed to other antibiotics.

As to the claimed amphotericin, like Vaghefi, Burns et al teaches that this drug (column 5 line 66) is deliverable by dry powder inhalers (column 3 line 59). Thus, one of ordinary skill would deliver this drug too in the method of Edwards et al in view of its deliverability,

↳ In a dry powder inhaler as taught by Burns et al.

Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1 "substantially" is vague; what %?

No claims allowed.

Any inquiry concerning this communication should be directed to Edward J.

Webman at telephone number 571-272-0633.

Webman/tgd

October 4, 2004

EDWARD J. WEBMAN
PRIMARY EXAMINER
GROUP 1500